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Food and Drug Administration  
5600 Fishers Lane  
Room 12A-16  
Rockville, MD 20857

**Docket 01N-0397**

Dear FDA:

The NTSB properly identifies a cause of concern – problems in understanding by the public and transportation professionals that medicinals can have adverse effects on performance and public safety.

More fine print on labels is likely an unrealistic answer since as the industry knows few consumers adequately read and understand this fine print. Perhaps, consideration for the procedure in other countries recognized in the 1/13/2000 NTSB report is appropriate – using a label (and advertising) symbol, complemented with a consistent industry education campaign. After studying liability litigations over the past thirty years, it would appear that fine print on labels and in advertising is used more for litigation defense than consumer communication.

Medicinals are recognized for causing deleterious driving, flying, boating and parachute performance. I was reminded over this past weekend during a Certificated Flight Instructor refresher clinic that pilots often experience such CNS effects...but do not understand or properly respond to them. Many drugs are specifically banned in aerobatic competition and airshows, disqualifying contestants and performers if used in order to protect the pilot and the nearby public. I know that marketers of various OTC medications, eg decongestants and antihistamines, alone or in combination, know that some medicinal products routinely cause CNS effects (symptoms of feeling wired, a buzz, sedation, euphoria, confusion, feeling distant or disconnected, slowed reaction time etc, as well as more serious morbidity and mortality).

This problem occurs beyond recognized medicinals with the explosion of dietary supplements sold to affect the CNS, or producing CNS adverse reactions. Too many purported dietary supplements heavily push the message of CNS augmentation. Certain

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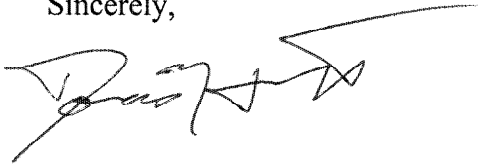
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dietary supplements are actually traditional herbal medicines/drugs recognized for thousands of years for their adverse effects.

Ephedra is simply one example, banned by the US Marines, IOC and NCAA. The attached 1998 Federal Air Surgeon advisory added to the recognition of problems with ephedra use.

Sincerely,

A handwritten signature in black ink, appearing to read 'Tiedt', with a long horizontal line extending from the end of the signature.

## The Federal Air Surgeon's Column

### Thin and Alert or Fat and Sleepy?

#### *Caution Pilots About Ephedrine*

By Jon L. Jordan, MD, JD

**Health-conscious users** of over-the-counter medications are responsive to advertisers claiming or suggesting that their products offer such positive effects as weight loss, euphoria, increased sexual sensations, heightened awareness, plus increased energy and alertness.

As with all over-the-counter drugs, we in aviation medicine advise airmen to emphasize caution when using any substance that may hinder their performance.

The Federal Aviation Administration recently learned of an instance where an airline pilot publicly advocated the use of an herbal product whose major ingredient was a botanical form of ephedrine. The airline pilot, who used ma huang, an ephedrine product for weight loss, was quoted as saying that he believed his passengers preferred a "thin, alert pilot" to a "fat, sleepy one." While the "slim look" may be in vogue, the potential for an incapacitation should make one reconsider.

Clinical evidence suggests that ephedrine, an amphetamine-like stimulant, is not appropriate for over the counter use by pilots.

The airline pilot apparently believes that ma huang, the herbal product he promotes, is safe for consumption as a dietary supplement to enhance weight loss, with the positive effect of enhancing mental alertness. Regardless of its form, ephedrine is a stimulant with the potential for serious, adverse cardiovascular effects.

The Food and Drug Administration (FDA) warns consumers about ephedrine's potential for adverse effects: heart attack, stroke, seizures, psychosis, and death. Clinically less significant effects include dizziness, nervousness, insomnia, tremors and headache, gastrointestinal distress, irregular heartbeat, and heart palpitations.

Since 1994, the FDA has investigated more than 800 reports of adverse effects associated with the use of these products. Most of the reported adverse events occurred in young to middle-aged, but otherwise healthy, adults using the products for weight control and increased energy. After seeking public comment, FDA researchers reviewed the scientific literature, public comments to the agency, and the suggestions of an expert advisory committee to assist in preparing a final rule, which is pending. The closing date for comments was August 18, 1997.

Because ephedrine alkaloids used in dietary supplements are heart and nervous system stimulants, those with hypertension, heart conditions and neurologic disorders should avoid their use. Also, pregnant women should avoid the use of dietary supplements with ephedrine alkaloids.

The FDA has stopped short of an outright withdrawal from the market of ephedrine-based products because, by law, such "dietary supplements" may not be regulated unless the FDA, on a case-by-case basis, can meet the legal burden of proving the marketed substance is unsafe. Thus, the FDA issued a statement warning potential users of the potential adverse effects of ephedrine-containing dietary supplements with labels that portray the products as alternatives to illegal street drugs (1). Next, they proposed safety measures to limit the amount of ephedrine alkaloids in products and to change labeling and marketing measures to reduce the risk to consumers (2).

Ingredient panels on diet supplement containers that have ephedrine among its ingredients may list ma huang, Chinese ephedra, ma huang extract, ephedra, Ephedra sinica, ephedra extract, ephedra herb powder, or epitonin, all of which indicate a source of ephedrine.

We welcome the FDA's actions and plans for closer regulation of such dietary supplements, as this provides a more solid basis for our recommendations that airmen should avoid ephedrine-based products. Aviation medical examiners must be aware of the dangers of so-called health or dietary supplements that contain ephedrine. If you have the opportunity, advise your pilot applicants to carefully consider the potential benefits versus the potential for disaster. As with the recent diet medication controversy, pilots should be cautioned about the potentially adverse effects of ephedrine (3).

(1) Statement on Street Drugs Containing Botanical Ephedrine, April 10, 1996.

(2) June 2, 1997.

(3) Weight and Balance, *FASMB*, page 1, Fall 1997

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Last modified April 6, 1998